1. 510(k) Summary of Safety and Effectiveness

K061241

JUL 28 2006

Device Name:	BioLucent Applicator
Device Model Numbers:	**RTA-06** **RTA-08** **RTA-10**
Classification Name:	Remote Controlled Radionuclide Applicator System (JAQ), 21 CFR, 892.5700
Device Classification:	Class II
Predicate devices:	NoviSad Rectal Applicator (Nucletron, B.V.) Wright Vaginal Cuff Applicator (K980601) Comfort Catheters (K032372) H.A.M. Applicator (K961601)
Manufacturer:	BioLucent, Inc. 6 Journey, Suite 325 Aliso Viejo, CA 92656
Establishment Registration Number:	2032338
Official Contact:	Sheryl Higgins BioLucent, Inc. 6 Journey, Suite 325 Aliso Viejo, CA 92656 Phone: (949) 349-1380 (x101)

Intended Use:
The BioLucent Applicator is intended for use as an accessory to commercially available remote afterloading equipment used during brachytherapy procedures. The multiple lumens of the BioLucent Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

Device Description:
The BioLucent Applicator is an expandable cylindrical device with radially positioned catheters, which is inserted into the target volume. The BioLucent Applicator is provided sterile and is a single use device.

Technological Characteristics Summary
The BioLucent Applicator is equivalent to the predicate devices, with the same principles of operation and overall technological characteristics.

Performance Data Summary
Performance testing was conducted on the BioLucent Applicator to demonstrate the integrity, suitability and substantial equivalence of the device.

Conclusion:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the BioLucent Applicator is determined to be substantially equivalent to existing legally marketed devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 2 8 2006

Mr. J. David Campbell
Director of Operations
BioLucent, Inc.
6 Journey, Suite 325
ALISO VIEJO CA 92656

Re: K061241
Trade/Device Name: BioLucent Applicators Model RTA-06, RTA-08 and RTA-10
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: June 27, 2006
Received: June 28, 2006

Dear Mr. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 061241

Device Name:

BioLucent Applicator

Indications for Use:

The BioLucent Applicator is intended for use as an accessory to commercially available remote afterloading equipment used during brachytherapy procedures. The multiple lumens of the BioLucent Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061241